

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flucloxacillin Capsules BP 250 mg
Flucloxacillin Capsules BP 500 mg

Please read this leaflet carefully before you start taking your medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1. What Flucloxacillin Capsules are and what they are used for

Your capsules are called Flucloxacillin Capsules BP 250mg or 500mg.

Flucloxacillin is an antibiotic for treating infections. It belongs to a group of antibiotics called “penicillins”. Flucloxacillin works by killing the bacteria that can cause infections.

2. Before you take Flucloxacillin Capsules

Let your doctor know if any of the following apply to you:

- You have ever had a skin rash or swelling of the face or neck when taking an antibiotic
- You know that you are allergic to penicillin, any other antibiotic or to any of the other ingredients in this medicine
- You have ever had a serious complaint – when taking an antibiotic
- You are being treated for kidney problems or gout
- You are being treated for liver problems
- Side effects in the elderly and those with serious liver problems may be particularly serious (sometimes fatal) so it is very important to tell your doctor if this applies to you
- You are pregnant, think you might be pregnant or are breastfeeding;
- You are 50 years old or older

- You are on a low sodium diet
- You are already taking any of the following medicines:
 - Probenecid (to prevent gout)
 - Methotrexate
 - Anticoagulants (used to prevent blood clots e.g. warfarin)
 - Any other antibiotics (to treat infection)
- You are taking other medicines including ones that you have bought for yourself without a prescription

If any of the above apply to you, your doctor may decide to prescribe a different medicine or change the dose of flucloxacillin.

Prolonged use of an antibiotic can occasionally lead to resistance, which means that your medicine may no longer be effective. If you have been taking this medicine for a long time, you should discuss your treatment with your doctor.

This medicine contains approximately 13 mg sodium per capsule in 'Flucloxacillin Capsules BP 250mg', and approximately 25mg sodium per capsule in 'Flucloxacillin Capsules BP 500mg'. To be taken into consideration by patients on a controlled sodium diet.

If you see another doctor or visit hospital, remember to tell them what medicines you are already taking.

3. How to take Flucloxacillin Capsules

You must take your capsules as you doctor has told you to. The label will tell you how much to take and how often to take it.

Swallow the capsules whole with a glass of water half to one hour before meals.

You may feel better after a few days of taking your medicine. Do not stop taking your medicine until you finish your prescribed course of treatment. If you stop taking your capsules before the end of the course, some bacteria may survive and cause the infection to come back.

Adults usually have to take one to two 250 mg capsules three times a day. Your doctor may prescribe a different dose for severe infections.

For infections of the joints (osteomyelitis) or heart (endocarditis) the usual dose is up to 8 g daily in divided doses six to eight hourly.

The usual dose for children (aged 2-10 years) is half the adult dose. For children (under 2 years) quarter the adult dose.

If you have kidney problems your doctor may tell you to take a lower dose or extend the period between doses.

If you forget to take a dose at the right time:

Take it as soon as you remember, but **do not** take two doses together. If it is almost time to take the next dose wait until then and then carry on as before.

What to do if you take too many capsules

It is important not to take too many capsules.

Contact your nearest hospital casualty department or a doctor for advice if you have swallowed too many capsules or if you think a child has swallowed any.

Take this leaflet and any capsules that you still have to show the doctor.

4. Possible side effects

A few people may find that this medicine gives them diarrhoea (several loose bowel movements a day). It may sometimes give you indigestion or make you feel sick (nausea) or occasionally be sick (vomiting). If this happens the symptoms are usually mild. If these symptoms continue or become severe, tell the doctor.

Allergic reactions can occur occasionally. Tell the doctor immediately if you start to itch or develop a rash.

Very rarely, flucloxacillin may be associated with more severe side effects: If the following symptoms occur, stop taking your medicine and seek immediate medical treatment:

- a swollen face and difficulty in breathing
- a rash with blisters that may cause the skin to peel, flake or bleed, and which may be accompanied by fever
- blisters on the lining of the mouth, throat, eyes, anus or genital region

If the following symptoms occur, tell your doctor as soon as possible:

- effects relating to the liver. These may appear as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine. These liver effects could occur up to 2 months after taking the medicine
- effects relating to the digestive system e.g. severe diarrhoea which may be bloody and be accompanied by abdominal cramps
- kidney disease – problems with urination, possibly painful and bloody
- a lack of white blood cells which may result in frequent infections such as fever, severe chills, sore throat or mouth ulcers
- a low platelet count which may result in bleeding or bruising more easily than normal
- breakdown of red blood cells (causing anaemia) may lead to tiredness, breathlessness, light-headedness, a rapid weak pulse or palpitations, headaches or yellowing of the skin and eyes

- muscle ache, joint pains and fever have occasionally occurred.

If you develop any unusual discomfort while taking your medicine, tell the doctor as soon as possible.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flucloxacillin Capsules

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original container in order to protect from moisture.

Do not take the capsules after the Expiry date (stated as 'Expiry') on the tub label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Flucloxacillin Capsules contains

Each Capsule contains:

The active substance:

- Each capsule contains flucloxacillin 250 mg as flucloxacillin sodium or flucloxacillin 500 mg as flucloxacillin sodium;

The other ingredients:

- Magnesium stearate, gelatin, titanium dioxide (E171), patent blue V (E131), erythrosine (E127).

What Flucloxacillin Capsules looks like and contents of pack

Flucloxacillin Capsules are hard, opaque, blue capsules printed with a twin triangle logo and 'FXN 250' (250mg) or 'FXN 500' (500mg).

The capsules come in packs of 100, 250, 500 or 1000.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Your capsules are made by Clonmel Health-Care Ltd., Waterford Road, Clonmel, Co. Tipperary.

The MA Holder is Norton Healthcare Ltd., Albert Basin, Royal Docks, London E16 2QJ, England.

This information only applies to Flucloxacillin capsules BP which are distributed by Norton Waterford, Unit 301, Waterford Industrial Park, Waterford, Ireland.

PA 282/41/1-2

This leaflet was revised in December 2015.